

Sherrie R. Savett (*pro hac vice*)
Joy P. Clairmont (*pro hac vice*)
Michael T. Fantini (*pro hac vice*)
William H. Ellerbe
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Telephone: 215-875-3000
ssavett@bm.net
jclairmont@bm.net
mfantini@bm.net
wellerbe@bm.net

Pete Marketos (*pro hac vice*)
Joshua M. Russ (*pro hac vice*)
Andrew O. Wirmani (*pro hac vice*)
REESE MARKETOS LLP
750 N. St. Paul Street, Suite 600
Dallas, TX 75201
Telephone: 214-382-9810
pete.marketos@rm-firm.com
josh.russ@rm-firm.com
andrew.wirmani@rm-firm.com
Attorneys for Relators

*(Additional Counsel Appear on
Signature Page)*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,
et al. EX REL. JESSICA PENELOW
and CHRISTINE BRANCACCIO,

Plaintiffs,

v.

JANSSEN PRODUCTS, LP,

Defendant.

Case No. 12-7758 (ZNQ)(JBD)

**RELATORS' REPLY BRIEF IN SUPPORT OF THEIR
MOTION FOR ENTRY OF JUDGMENT**

TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
I. RELATORS’ REQUESTED DAMAGES AWARD IS JUSTIFIED.....	4
A. The Court should award treble damages to the States	5
1. Relators’ state-law claims are supported by ample evidence ..	5
2. There is no “apportionment” requirement between the States.	6
3. The Court’s instructions were correct.....	10
B. Relators are entitled to judgment for the federal FCA damages	10
II. RELATORS’ REQUESTED PENALTIES ARE APPROPRIATE.....	12
A. There is no “allocation” of penalties among the state governments...	12
B. The requested penalties are proper	13
1. The requested penalties are based on Janssen’s conduct	14
2. The requested penalties are constitutional and appropriate under the law	15
a) The requested penalties are constitutional	17
b) The assessment of a \$9,000 penalty per false claim is warranted and necessary	19
CONCLUSION	20

TABLE OF AUTHORITIES

CASES

<i>Barber v. Whirlpool Corp.</i> , 34 F.3d 1268 (4th Cir. 1994).....	7
<i>BMW of North America, Inc. v. Gore</i> , 517 U.S. 559 (1996).....	17, 20
<i>Cook Cnty. v. United States. ex rel. Chandler</i> , 538 U.S. 119 (2003).....	16
<i>Gibson v. Moskowitz</i> , 523 F.3d 657 (6th Cir. 2008).....	9
<i>Hailey v. City of Camden</i> , 631 F. Supp. 2d 528 (D.N.J. 2009)	7
<i>Inter Medical Supplies Ltd. v. EBI Medical Systems, Inc.</i> , 975 F. Supp. 681 (D.N.J. 1997)	7
<i>Jurinko v. Med. Protective Co.</i> , 305 F. App'x 13 (3d Cir. 2008).....	15-16
<i>Passantino v. Johnson & Johnson Consumer Prods., Inc.</i> , 212 F.3d 493 (9th Cir. 2000).....	9
<i>U.S. ex rel. Putnam v. Eastern Idaho Regional Medical Center</i> , 696 F.Supp.2d 1190 (D. Idaho).....	13
<i>United States ex rel Hayes v. CMC Elecs., Inc.</i> , 297 F. Supp. 2d 734 (D.N.J. 2003)	19
<i>United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.</i> , 741 F.3d 390 (4th Cir. 2013).....	13, 16, 18-19
<i>United States ex rel. Drakeford v. Tuomey</i> , 792 F.3d 364 (4th Cir. 2015).....	17

<i>United States ex rel. Fahner v. Alaska</i> , 591 F. Supp. 794 (N.D. Ill. 1984)	15
<i>United States ex rel. Kreindler & Kreindler v. United Tech. Corp.</i> , 985 F.2d 1148 (2d Cir. 1993).....	14
<i>United States ex rel. Landsberg v. Argentis Medical, P.C.</i> , No. 03-1263, 2009 WL 10727191 (W.D. Pa. 2009)	13
<i>United States ex rel. Morsell v. Gen Digital, Inc.</i> , No. CV 12-800 (RC), 2024 WL 166015 (D.D.C. Jan. 16, 2024)	16
<i>United States ex rel. Sanders v. Am.-Amicable Life Ins. Co. of Texas</i> , 545 F.3d 256 (3d Cir. 2008).....	19
<i>United States v. Bajakajian</i> , 524 U.S. 321 (1998)	16-17
<i>United States v. Bornstein</i> , 423 U.S. 303 (1976)	15-16
<i>United States v. Ehrlich</i> , 643 F.2d 634 (9th Cir. 1981).....	14
<i>United States v. Incorporated Village of Island Park</i> , 888 F. Supp. 419 (E.D.N.Y. 1995).....	14
<i>United States v. Mackby</i> , 339 F.3d 1013 (9th Cir. 2003).....	13, 18
<i>United States v. Rogan</i> , 517 F.3d 449 (7th Cir. 2008).....	17
<i>United States v. Teva Pharms. USA, Inc.</i> , No. 13 CIV.3702 (CM), 2019 WL 13244252 (S.D.N.Y. July 1, 2019).....	14-15

Relators’ Motion for Entry of Judgment asks the Court to enter judgment on the jury’s unanimous verdict under Rule 58. It requests that the Court apply treble damages under the federal and state False Claims Acts and assess a penalty per false claim under the federal FCA within the range prescribed by Congress. To support the Court’s assessment of Relators’ requested penalty amount, Relators’ motion addresses the trial evidence and Janssen’s conduct under the “totality of the circumstances” factors that district courts in FCA cases must consider. None of these concepts are novel.

Undeterred by the weight of the evidence at trial and the proper legal standards, however, Janssen continues to cry foul and throw up roadblocks to judgment. After gambling on a jury trial in an FCA case in which it presented no alternative damages theory, Janssen now wants to avoid the result of its own losing wager. And despite claiming victory—arguing that Relators “lost the majority of their case”—Janssen demands at the same time that the whole verdict be cast aside by concocting an endless parade of horrors.

First, Janssen attacks the jury’s entire damages award by challenging the state-law FCA claims—recycling much of the errant argument from its post-verdict motions and manufacturing confusion over disparate, irrelevant state Medicaid program requirements. It then winds its way backward through the verdict form to argue that the jury’s findings on *federal* FCA damages and the number of false

claims are hopelessly infected by the purportedly infirm state-law claims. Finally, Janssen complains about the legislatively mandated result of its misconduct, insisting it should not be liable for a civil penalty for each of the false claims the jury found it caused and that the penalties requested by Relators—in the middle of Congress’s prescribed range—are unconstitutionally excessive.

The Court should not be persuaded by Janssen’s intentional confusion of the issues. Relators provided a mountain of evidence proving that *no* government payor, whether Medicare, ADAP, or Medicaid, would pay for prescriptions caused by Janssen’s false and misleading OL marketing in violation of FDA law. Janssen therefore caused claims to be submitted that were not eligible for reimbursement and would have affected the payment decisions of every single payor.

Relators *also* proved that Janssen’s illegal OL marketing caused the submission of claims for prescriptions that were not for medically accepted indications or were not medically necessary or reasonable. The Court instructed the jury, in Instruction No. 17, to consider those designated conditions of payment as to Medicare Part D, Medicaid, and ADAP. The resulting false claims were therefore materially false as to every single government payor. *End of story.*

The jury separately found liability and damages as to the United States and the States, and it found the number of false claims submitted in violation of the federal FCA. Janssen’s complaint about the allocation of damages *between* the States

has nothing to do with the integrity of the jury's damages award *to* the States and has no bearing on the jury's award of damages to the United States.

It is wholly irrelevant whether each individual state Medicaid program imposes different conditions for the reimbursement of a wheelchair, or for medical services for parents with dependent children, or anything else. What matters is what Relators proved with respect to their claims *in this case*—that *no* government payor would have reimbursed the prescriptions caused by Janssen's illegal marketing.

Janssen's contrived confusion over the jury's assessment of the number of false claims is likewise meritless. The jury found that Janssen's unlawful promotion violated the federal FCA and caused 159,574 false claims to be submitted. There is no dilemma over what civil penalty to award to any state government, as Janssen now claims, because Relators' motion seeks civil penalties only to the United States based on the jury's verdict.

Finally, Janssen's feeble effort to lower the number of false claims it is liable for directly contradicts the jury's verdict and FCA caselaw confirming that Janssen must pay a penalty for each of the false claims it caused to be submitted. And there is no constitutional concern regarding civil penalties where the penalty range itself is prescribed by Congress and Relators seek less than the maximum penalty. Regardless, the proposed penalty is well within any constitutional limit under FCA caselaw.

At bottom, Janssen’s fraudulent marketing scheme caused an enormous number of false claims to be submitted to government healthcare programs. While the resulting damages and fines no doubt cause Janssen dismay, it chose to engage in a 9-year, illegal marketing scheme that misrepresented the safety and appropriate use of potent drugs for tens of thousands of HIV patients—causing substantial financial harm and posing incalculable health risks to patients. During the same period, Janssen was the subject of two separate enforcement actions and CIAs for substantially similar conduct with other drugs. If ever there were a candidate for deterrence, Janssen is it. Relators request that the Court enter judgment on the verdict.

I. RELATORS’ REQUESTED DAMAGES AWARD IS JUSTIFIED.

Janssen begins by contesting entry of judgment on the jury’s verdict for damages to the United States and the States, repeating most of the arguments in its post-verdict motions.¹ It complains that “Relators frame this request as a straightforward entry of treble damages on the jury’s single damages award.” Def. Br. at 4. But Relators “frame” the issue as straightforward because *it is*—in

¹ Relators incorporate herein the entirety of the arguments and evidence set forth in their Opposition to Janssen’s Motion for Judgment as a Matter of Law (“Rel. Br. Rule 50(b)”), *see* Dkt. 481, and their Opposition to Janssen’s Motion for New Trial (“Rel. Br. MNT”), *see* Dkt. 480. “Def. Br.” refers to Janssen’s Opposition to Relators’ Motion for Entry of Judgment, Dkt. 479.

accordance with the jury's verdict, the federal and state FCAs, and the legal standard for entry of judgment. No amount of dust-kicking by Janssen about issues of proof, "state-law claims," jury instructions, or a "jury compromise" can change that fact.

A. The Court should award treble damages to the States.

To avoid damages on Relators' state-law claims, Janssen ignores the trial evidence, manufactures an "apportionment" requirement, and rehashes the same misguided attacks on the Court's instructions from its post-verdict motions. All of these arguments fail.

1. Relators' state-law claims are supported by ample evidence.

Janssen claims that Relators cannot recover any damages to the States because they failed to prove their state-law claims entirely. Def. Br. at 5. Janssen spends five pages explaining state Medicaid programs and what it contends Relators had to prove as to each of 26 states *individually* to prevail on their state-law claims. Def. Br. at 5-11. But the overwhelming evidence at trial established that *no* government payor, including *Medicaid* payors, would pay for prescriptions resulting from Janssen's illegal OL promotion of its drugs. *See* Rel. Br. Rule 50(b) at 19-26, 29-34.

In finding liability, the jury was specifically instructed to determine whether Relators proved that Janssen's "*off-label marketing violations*" were material to the government's payment decisions, *see* Dkt. 424-11 at 37 (Instruction No. 19.4,

“Materiality”), and it found that Janssen violated the federal and state FCAs by “*unlawfully promoting*” Prezista or Intelence. *See* Dkt. 435 at 3, 5 (Verdict Form).

Relators thus proved that Janssen’s illegal marketing caused materially false prescriptions to be submitted for reimbursement to *all three* programs—Medicare, ADAP, and *Medicaid*. There was no need for state-by-state proof that the claims submitted to *each* state’s Medicaid program were materially false when the evidence established they were materially false as to *every* state program.

The same goes for the two expressly designated conditions of payment, which apply to Medicare, ADAP, *and Medicaid* as the Court instructed. *See* Rel. Br. Rule 50(b) at 49-56. Relators proved that Janssen’s illegal marketing caused claims to be submitted that violated both conditions,² which were false claims as to *all* state Medicaid programs. No matter how hard Janssen tries, it cannot complicate the simplicity of “none” or “all.”

2. There is no “apportionment” requirement between the States.

Janssen next argues that the Court may not enter judgment where a “general” verdict “leave[s] no basis to apportion the commingled damages between” the 26

² Relators’ claims data expert, Ian Dew, testified extensively about the claims submitted to the Medicaid programs for reimbursement and that he was asked to identify “Medicare *and Medicaid* claims that are *consistent with the allegations in this case*[.]” 5/31/24 Tr. 5220:25-5221:2 (emphasis added); *id.* at 5246:15-5247:4; *see* Rel. Br. Rule 50(b) at 48-49.

states. Def. Br. at 11. It claims, citing two cases, that “[c]ourts consistently refuse to enter judgment” where a jury “issues a combined damages award that does not distinguish between parties’ separate claims.” *Id.* Janssen is wrong.

The jury found Janssen liable for violating every one of the States’ identical FCAs and awarded damages that the States “sustained as a result” of those violations. Both the liability and damages findings are supported by substantial evidence. Janssen does not allege that a liability finding as to one of the States is unsustainable versus the remaining States such that allocation between them is necessary—the circumstances present in the two cases it cites.³

To the contrary, this Court rejected an “allocation” challenge from the losing defendants in *Inter Medical Supplies Ltd. v. EBI Medical Systems, Inc.*, 975 F. Supp. 681, 691 (D.N.J. 1997), after a two-month trial that resulted in a \$150 million jury verdict for plaintiffs. The jury found all defendants liable to all three affiliated

³ See *Hailey v. City of Camden*, 631 F. Supp. 2d 528, 537 (D.N.J. 2009) (ordering new trial on punitive damages where jury was incorrectly instructed that it could award punitive damages against the City under the federal statute and did not distinguish between federal and state claims in awarding punitive damages); *Barber v. Whirlpool Corp.*, 34 F.3d 1268, 1278 (4th Cir. 1994) (ordering new trial on damages after jury found defendant liable for intentional infliction of emotional distress and malicious prosecution, the damages did not differentiate between claims, and the intentional infliction tort was reversed on appeal).

plaintiffs and awarded a single compensatory amount in lost profits to all three plaintiffs collectively for separate tort and contract claims. *Id.* at 691.

Defendants moved for judgment as a matter of law, arguing that plaintiffs “failed to present evidence attributing the damages to each [plaintiff] entity and each claim.” *Id.* (emphasis added). The court rejected that requirement, holding that “no such testimony was required” because “all of the claims upon which plaintiffs prevailed arose from the same set of facts,” and the damages award need not be “assigned a given legal theory.” *Id.* Moreover, the court held that the defendants could not “impugn the jury’s verdict simply by asserting that the damages testimony was ‘undifferentiated’” between affiliated plaintiffs. *Id.* (emphasis added). To have “required separate damages figures for each entity” would have “invited confusion and a greater potential for an excessive or duplicative compensatory award.” *Id.*⁴ Relators’ counsel made these same points during trial.⁵

⁴ As the court noted at the outset of its opinion: “Following a two month trial, at which the jury heard more than 5000 pages of testimony and endured numerous lengthy hiatuses while the parties debated points of law, the jury deliberated for over two days before reaching the verdict described above. It would disserve the jury system and dishonor the contribution of this dedicated jury to that system were the verdict to be lightly overturned.” *Id.* at 685.

⁵ 6/11/24 Tr. 7905:17-20 (“And I’m not sure I’m aware of any requirement that you have to go through each state and apportion that money when they are co-plaintiffs trying to get the same bucket of damages.”); *see id.* at 7902:6-20.

Janssen, of course, creates as much noise over apportionment as possible, attempting to leverage the Court's concerns regarding this issue in the verdict form prior to closing. Def. Br. at 12-14. Janssen omits the Court's competing concern that Janssen's proposed verdict sheet would have been "unbelievably confusing" to the jury. 6/11/24 Tr. 7896:19-20. Nonetheless, Relators addressed the Court's concern regarding the question for the number of false claims, as the Court noted, *id.* at 7909:9-17, and liability questions for each of the States were added. *Id.* at 7911:6-22. The verdict form has all the necessary, discrete findings for entry of judgment.

But even if apportionment between the States *were* required, there is no basis for Janssen's contention that the Court cannot do so. Where necessary, the responsibility to allocate damages between claims is "a task often left to trial judges." *Gibson v. Moskowitz*, 523 F.3d 657, 667 (6th Cir. 2008) (where the jury did not apportion damages, the task was left to trial court's discretion) (quoting *Passantino v. Johnson & Johnson Consumer Prods., Inc.*, 212 F.3d 493, 509 (9th Cir. 2000) ("[T]he district court generally has discretion regarding how to allocate the damage award.")). If it believes apportionment is necessary, the Court may take judicial notice of the relative populations of each of the States and apportion accordingly.⁶

⁶ To be clear, Relators contend that an allocation exercise as between the States, all of which are members of the National Association of Medicaid Enforcement Units ("NAMFCU") and can allocate among themselves after judgment, is unnecessary. It

3. The Court’s instructions were correct.

Janssen next argues, again, that the Court’s Instruction Nos. 23 and 26 “independently preclude entry of judgment” because they were erroneous and “may have influenced” the jury’s verdict. Def. Br. at 14. These are substantially the same arguments that Janssen raised in its Motion for New Trial, which Relators fully responded to and refuted. *See* Rel. Br. MNT at 5-15.

It is most telling, however, that Janssen still cannot point to *any* state’s Medicaid coverage requirements that conflict with the Court’s instructions to the jury regarding express conditions of payment. *See id.* at 9-10. Instead, it continues to speculate about what state Medicaid requirements *may* cover. Def. Br. at 10; *see* Rel. Br. MNT at 7-12 (Janssen has *waived* any objection to these instructions).

B. Relators are entitled to judgment for the federal FCA damages.

Janssen also contends that Relators are not entitled to judgment for treble damages on the jury’s federal FCA verdict in the amount of \$360,014,208. Here, Janssen employs its “reverse infection” theory and claims that “Relators’ failure to prove their state claims also invalidates the jury’s federal damages award.” Def. Br. at 17. According to Janssen, because Medicaid is jointly funded by the state and

is even more unnecessary to spend the Court’s resources with a retrial on *allocation* of damages between the States—but even if the Court finds it necessary, that allocation has no effect on the remainder of the judgment.

federal governments, “some portion of the jury’s federal damages award must be based on federal funding” for the state Medicaid claims. *Id.*

This argument is baseless. Relators argued to the jury that damages for Medicare and ADAP go to the United States under the federal FCA and damages to the state Medicaid programs (the *entire* amount) go to the States under the state FCAs. *See* Rel. Br. MNT at 22-24 and n.25; *see* Instruction No. 23 (“State Law Claims”) (addressing Medicaid). That is precisely what CMS policy requires when states seek recovery of Medicaid damages. *Id.* at n.26. There was no *evidence* before the jury and no *argument* as to any portion of Medicaid damages going partially to the federal government in a different blank. Janssen’s speculation here is contrived to create a problem.⁷

Finally, Janssen rehashes its post-verdict challenges and argues that the Court should not enter judgment “for all the reasons explained in Janssen’s JMOL and New Trial Motions[.]” Def. Br. at 18-21. Relators fully responded to and refuted

⁷ Janssen’s assertion that Relators’ counsel “admitted” that the federal FMAP portion of state Medicaid damages would result in damages for Medicaid being included in the federal damages award, Def. Br. at 17, is exceptionally misleading. Relators’ counsel merely explained to the Court that there is overlap between federal and state funding when Medicaid is involved and that the verdict form revisions were intended “to make this streamlined so that we are *not* overlapping.” 6/11/24 Tr. at 7899:20-21 (emphasis added).

these arguments. The Court should deny Janssen's arguments and enter judgment for treble damages on Relators' federal FCA claim.

II. RELATORS' REQUESTED PENALTIES ARE APPROPRIATE.

Janssen's attack on Relators' requested civil penalties again consists of an effort to confuse and complicate. Of its 20 pages of argument, Def. Br. at 21-40, Janssen spends the bulk of its time concocting a procedural quagmire with the verdict form in the hope it will prevent entry of judgment entirely. Janssen spends a scant four pages at the end addressing the trial evidence of its misconduct. *Id.* at 37-40.

But the jury's findings that Janssen's unlawful promotion violated the federal FCA and caused the submission of 159,574 false claims are straightforward. *See* Dkt. 435 at 3 (Verdict Form). Relators specifically seek statutory penalties only for the false claims under the federal FCA. Rel. Br. MEJ at 2, 6-23. An award of civil penalties between \$877,657,000 and \$1,755,314,000 is mandated by statute, with the Court determining that amount by evaluating the trial evidence. *Id.* at 7.

A. There is no "allocation" of penalties among the state governments.

Janssen claims it is "impossible for the Court to determine the appropriate amount of penalties *payable to the states*" because the false claims are "undifferentiated." *See* Def. Br. at 21-25 (emphasis added). Fortunately, the Court need not tackle this "impossible" task because Relators did not ask the jury to find the number of false claims under the *state* FCAs. Doing so would have been

potentially duplicative.⁸ While Janssen attempts to distort the trial transcript, Relators' counsel discussed the issue of overlap with the Court.⁹ Relators do not seek penalties for the state-law violations,¹⁰ so Janssen's manufactured concern for a civil penalty "apportionment" is unwarranted.

B. The requested penalties are proper.

Finally, Janssen insists that (1) "Relators' requested penalties would punish Janssen for the acts of doctors rather than for its own acts, and [(2)] are unconstitutionally disproportionate to the actual damages the jury found." Def. Br.

⁸ A false claim submitted to a state Medicaid program—while a violation of that state's FCA—is nonetheless a violation of the *federal* FCA. *U.S. ex rel. Putnam v. Eastern Idaho Regional Medical Center*, 696 F.Supp.2d 1190, 1200 (D. Idaho). And false claims submitted to state Medicaid programs entitle the United States to civil penalties under the federal FCA. *See United States ex rel. Landsberg v. Argentis Medical, P.C.*, No. 03-1263, 2009 WL 10727191, at *6 (W.D. Pa. 2009) (awarding \$6,143,500 in civil penalties for 1,117 false claims submitted to Medicaid on \$59,940.40 in single damages to the United States for a federal FCA claim).

⁹ 6/11/24 Tr. 7899:20-7900:3 ("MR. RUSS: . . . So we are trying to make this streamlined *so that we are not overlapping*. So, for instance, all the claims at issue that are federal claims and Medicaid claims will be in the false claims for both the first question and then later in the later questions, so there's some overlap. So we are trying to figure out *how to best apportion this so we don't have the jury answering questions, you know, that are overlapping on the number of claims*—THE COURT: Right. I get that.").

¹⁰ *See United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 405-07 (4th Cir. 2013) (relator is "master of [her] complaint," and discretion to take "lesser judgment" than she is entitled to is "virtually unbounded") (affirming judgment on relator's voluntary remittitur of \$24 million for civil penalties to avoid constitutional concerns) (citing *United States v. Mackby*, 339 F.3d 1013 (9th Cir. 2003)).

at 26. This argument is absurd in the face of the mountains of evidence presented at trial that Janssen engaged in the unlawful promotion of Prezista and Intelence to doctors, over the course of more than 9 years and through more than 620,000 marketing contacts,¹¹ for the express purpose of driving up prescriptions. Relators' proposed civil penalty also poses no constitutional concerns.

1. The requested penalties are based on Janssen's conduct.

Janssen argues that "Relators' requested penalties are improper because they would punish Janssen for the acts of others rather than for its own behavior." Def. Br. at 26. Janssen glosses over the jury's finding that *Janssen's unlawful promotion* caused 159,574 false claims to be submitted in violation of the federal FCA. Dkt. 435 at 3 (Verdict Form). Here, Janssen was not only aware that it was changing doctors' prescribing behavior, but that was its sales force's *entire goal*.

Janssen specifically tracked the increase in prescriptions of doctors its sales force unlawfully influenced. Where "a person knowingly causes a specific number of false claims to be filed, he is liable for an equal number of forfeitures." *United States v. Ehrlich*, 643 F.2d 634, 638 (9th Cir. 1981) (holding a defendant liable for all false claims submitted where he "knew a false claim would be submitted").¹² The

¹¹ See 5/31/24 Tr. 5236:13-17 (Dew).

¹² See also *United States ex rel. Kreindler & Kreindler v. United Tech. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993) (same); see also *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419 (E.D.N.Y. 1995) (same); see also *United States v. Teva Pharms. USA, Inc.*, No. 13 CIV.3702 (CM), 2019 WL 13244252, at

Court should assess a penalty for every act “which caused [another] to submit false claims to the Government” where it “did so knowing” the claim would be submitted for reimbursement. *United States v. Bornstein*, 423 U.S. 303, 313 (1976); *see Teva*, 2019 WL 13244252, at *5 (finding knowledge of the continued submission of false claims where Teva allegedly induced speakers to write prescriptions and “tracked the prescriptions its speakers wrote”). The 159,574 false claims were the intended and foreseeable result of Janssen’s OL marketing of Prezista and Intelence and assessing a penalty for each is appropriate. *See id.* (“The Court agrees with Relators that penalizing Teva for each prescription drug event is consistent with the holding of *Bornstein*[.]”).

2. The requested penalties are constitutional and appropriate under the law.

Janssen contends that Relators’ request for penalties are unconstitutionally high. Def. Br. at 29-31. It contends that courts “adjust FCA penalties to the lower end” of the statutory range in appropriate cases to “avoid constitutional issues.”¹³

*5 (S.D.N.Y. July 1, 2019) (when a [pharmaceutical manufacturer] has “knowledge of the continuing submission of false claims by an intermediary[,] . . . courts assess civil penalties based on the number of claims submitted, not any individual ‘act’ of the defendant”); *see also United States ex rel. Fahner v. Alaska*, 591 F. Supp. 794, 799-801 (N.D. Ill. 1984) (“impos[ing] forfeitures based on the number of false claims submitted” where the defendant “knew he was submitting false claims”).

¹³ Janssen attempts to skew the constitutional challenge with “Third Circuit precedent” that has no application to a False Claims Act analysis where civil penalties are legislatively mandated and Relators’ requested award is below the maximum penalty. Def. Br. at 30-31 (citing *Jurinko v. Med. Protective Co.*, 305 F.

There are no such issues here. *See also* Dkt. 484 (Govt.’s Statement of Interest opposing Janssen’s argument that the FCA’s *qui tam* provision is unconstitutional).

In determining whether civil penalties are constitutional, courts should consider: (1) the seriousness of the offense; (2) the harm caused; and (3) the maximum penalty the defendant faced. *United States v. Bajakajian*, 524 U.S. 321, 336 (1998). Courts should exercise great deference to penalties mandated by the legislature. *Id.* While FCA awards are subject to the Eighth Amendment’s limit on excessive fines, “proving a violation is a high bar.” *United States ex rel. Morsell v. Gen Digital, Inc.*, No. CV 12-800 (RC), 2024 WL 166015, at *8 (D.D.C. Jan. 16, 2024). The Supreme Court has held that a fine violates the Eighth Amendment only if “it is grossly disproportional to the gravity of [the] offense.” *Bajakajian*, 524 U.S. at 334. “This ‘test is by no means onerous’ and fines ordered pursuant to the FCA will only be found excessive ‘infrequent[ly].’” *Morsell*, 2024 WL 166015, at *7 (quoting *Gosselin*, 741 F.3d at 408). The requested award is both mandated by the

App’x 13, 28 (3d Cir. 2008) (applying constitutional ratio analysis in context of insurer’s bad faith failure to settle medical malpractice claim after *jury award* of punitive damages). Moreover, single damages here of \$150 million are not the appropriate measuring stick for calculating any “ratio,” as compensatory damages include at least *double* damages *plus* the relator’s share under Supreme Court precedent. *See United States v. Bornstein*, 423 U.S. 303, 314 (1976) (double damages necessary to make government “whole”); *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 129-34 (2003) (including relator’s share in compensatory analysis).

FCA and warranted by the reprehensibility of Janssen's conduct. It falls well within constitutional parameters.¹⁴

a) The requested penalties are constitutional.

Considering (1) the seriousness of the offense, (2) the harm caused, and (3) the maximum penalty Janssen faced, *see Bajakajian*, 524 U.S. at 336, Relators' requested penalty is justified. As to the seriousness of the offense, "[t]he degree of reprehensibility of the defendant's conduct is '[p]erhaps the most important indicium of the reasonableness of a punitive damages award.'" *Drakeford*, 792 F.3d at 388 (quoting *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 575 (1996)). As Relators have set forth at length, Janssen's conduct is nothing short of reprehensible. The jury found Janssen liable for unlawfully promoting Prezista and Intelence OL to doctors treating vulnerable HIV patients. Janssen pushed its sales team to market drugs for HIV patients they were not intended for, all while severely downplaying the risks to patient safety in order to expand market share and increase sales. The misuse of these drugs in HIV patients can have devastating impacts, including a

¹⁴ Moreover, "[t]here is no reason to believe that the [Supreme Court's] 'approach to punitive damages under the Fifth Amendment would differ dramatically from analysis under the Excessive Fines Clause.'" *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 388 (4th Cir. 2015) (citing *United States v. Rogan*, 517 F.3d 449, 454 (7th Cir. 2008)).

heightened risk of serious cardiovascular complications and *cardiac injuries*. See Rel. Br. 50(b) at 46-47; Rel. Br. MEJ at 9-15.

Janssen's conduct also caused substantial economic harm to the government. The jury found Janssen liable for over \$150 million in damages inflicted on government healthcare programs and borne by taxpayers. *Bunk*, 741 F.3d at 409.¹⁵

As to the final factor, the maximum penalty the defendant faced, the requested penalty of \$9,000 is well below the maximum \$11,000 penalty Janssen faces under the FCA and thus “*receive[s] a strong presumption of constitutionality.*” *Yates*, 21 F.4th at 1314 (quoting *Chaplin's*, 646 F.3d at 852) (emphasis added). This penalty does not become unreasonable or exorbitant merely because, when multiplied by the number of false claims Janssen caused, it reaches \$1.4 billion. The final penalty amount is only so high because *Janssen caused nearly 160,000 false claims* to be submitted to the Government for payment. “[T]he size of the award is a direct reflection of [Janssen's] repeated and knowing submission of false claims to the United States.” *Yates*, 21 F.4th at 1316.

¹⁵ See also *Yates*, 21 F.4th at 1316 (“Fraud harms the United States in ways untethered to the value of any ultimate payment.”). Conduct like Janssen's “shakes the public's faith in the government's competence and may encourage others similarly situated to act in a like fashion.” *Id.* at 409; see also *Killough*, 848 F.2d at 1532. In the healthcare context, “[f]raudulent claims make the administration of Medicare more difficult, and widespread fraud would undermine public confidence in the system.” *Mackby II*, 339 F.3d at 1019.

Further, the ratio between the actual damages and the total award requested here, including civil penalties, is substantially *lower* than in other FCA cases. The Eleventh Circuit approved an award of \$1.179 million, which was 1560.47 times the actual damages to the United States of \$755.54. *Yates*, 21 F.4th at 1314-16. And the Fourth Circuit in *Bunk* permitted a penalty of \$24 million even though the relator sought *zero* damages. 742 F.3d at 409.¹⁶ Thus, the total award in this case is well within the parameters considered reasonable by other courts, particularly taking into account Janssen's massive and prolonged fraud.

b) The assessment of a \$9,000 penalty per false claim is warranted and necessary.

Finally, Janssen argues the Court has “no credible reason” to assess a \$9,000 penalty per false claim. Def. Br. at 36-40. In truth, the requested \$9,000 penalty is less than Janssen has earned. The dismissive attitude with which Janssen breezes through the extensive evidence of its reprehensible conduct in this portion of its brief alone demonstrates that a higher civil penalty than Relators requested would be warranted. Def. Br. at 36-40.

¹⁶ In fact, courts in this Circuit have repeatedly affirmed that civil penalties are available for FCA violations even where the Government suffers *no* damages. *See, e.g., United States ex rel. Sanders v. Am.-Amicable Life Ins. Co. of Texas*, 545 F.3d 256, 259 (3d Cir. 2008) (“Sanders correctly notes that a party can be subject to FCA liability (i.e. civil penalties) even where the government suffers no monetary injury”); *United States ex rel Hayes v. CMC Elecs., Inc.*, 297 F. Supp. 2d 734, 737 (D.N.J. 2003) (noting that “even if the U.S. Government were unable to prove actual monetary damages, the false claims are still actionable under the FCA”).

As a prime example, Relators set forth the trial evidence demonstrating the risk to patient health and safety posed by Janssen's false and misleading promotion. Rel. Br. MEJ at 9-13. Janssen's casual rejoinder is that "no evidence at trial identified a single patient whose treatment was ineffective, or who suffered harm from Janssen's products." Def. Br. at 37. To begin with, even under the factors that *Janssen* contends are applicable to a constitutionality assessment, courts are to consider "the harm or *potential* harm suffered" and whether the conduct "evinced an indifference to or a reckless disregard of the health or safety of others." *BMW*, 517 U.S. at 575, 576; Def. Br. at 31. Moreover, the trial evidence showed not only that the *risk* of harm to patients was grave, but that Prezista patients had higher rates of *cardiac injuries* than its competitor drug Reyataz. Rel. Br. MEJ at 9-13.

The remainder of Janssen's half-hearted arguments regarding its egregious conduct are spurious. For instance, Janssen implies that it did not engage in a "top-down, nationwide . . . scheme" because the jury only found 159,574 false claims submitted to the government. Def. Br. at 38. Holding the current record for the most-ever false claims found by a civil jury is a dubious distinction. Relators request that the Court enter judgment and end this case.

CONCLUSION

For the foregoing reasons, Relators respectfully request that this Court enter the Proposed Final Judgment in the form submitted by Relators at Dkt. 475-2.

Date: November 15, 2024

Respectfully submitted,

By: /s/ William H. Ellerbe
William H. Ellerbe
Sherrie R. Savett (*pro hac vice*)
Joy P. Clairmont (*pro hac vice*)
Michael T. Fantini (*pro hac vice*)
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Tel: 215-875-3000
ssavett@bm.net
jclairmont@bm.net
mfantini@bm.net
wellerbe@bm.net

Pete Marketos (*pro hac vice*)
Joshua M. Russ (*pro hac vice*)
Andrew O. Wirmani (*pro hac vice*)
REESE MARKETOS LLP
750 N. St. Paul Street, Suite 600
Dallas, TX 75201
Tel: 214-382-9810
josh.russ@rm-firm.com
andrew.wirmani@rm-firm.com
pete.marketos@rm-firm.com

Peter S. Pearlman
COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP
Park 80 Plaza West-One
250 Pehle Avenue, Suite 401
Saddle Brook, NJ 07663
Tel: 201-845-9600
psp@njlawfirm.com
Counsel for Relators